

## **PD7 McCann Opp Exh 02**



## POM 1311 Practice Compliance Corresponding Responsibility - Proper Prescriber Patient Relationship

### Application

All pharmacy associates of Wal-Mart Stores, Inc. and its U.S. subsidiaries ("Walmart"), including Sam's Club and Puerto Rico associates.

### Overview

Under federal law, pharmacists may only dispense a controlled substance prescription issued for a legitimate medical purpose and based on a proper prescriber-patient relationship. Pharmacists must thoroughly evaluate controlled substance prescriptions and use their professional judgment to determine if it is appropriate to dispense.

### Corresponding Responsibility

Under the Controlled Substances Act, a pharmacist has a legal responsibility to only dispense controlled substance prescriptions that are written for a legitimate medical purpose in the usual course of professional treatment. This is often referred to as the pharmacist's "corresponding responsibility." According to 21 C.F.R. § 1306.04 (a):

The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, **but a corresponding responsibility rests with the pharmacist who fills the prescription.**

This regulation is used as the basis for nearly all criminal, civil, and administrative action taken by the DEA against pharmacies and pharmacists, and therefore should be one of the guiding principles by which you make decisions related to controlled substance dispensing.

### Red Flags

Pharmacists must review each controlled substance prescription carefully to determine if it is written for a legitimate medical purpose. Technicians must report any red flags or concerns to the pharmacist, and the pharmacist must resolve every red flag before filling the prescription. The following "red flags" may indicate a prescription was not issued for a legitimate medical purpose:

#### Prescriber Red Flags:

- Prescription is written by a prescriber outside of the pharmacy's trade area.
- Prescriber routinely prescribes a large number (or percentage) of prescriptions for controlled substances relative to prescriptions for non-controlled substances.
- Prescriber prescribes the same medication, with the same directions, for the same quantity for a large number of individuals.



**POM 1311**  
**Practice Compliance**  
**Corresponding Responsibility -**  
**Proper Prescriber Patient**  
**Relationship**

- Prescriber routinely writes for large doses of controlled substances.
- Prescriber provides the same diagnosis for the majority of individuals.
- Prescriber engages in the unauthorized practice of medicine, including writing prescriptions outside of scope of practice and/or not having a proper relationship with the patient.
- Prescriber is under investigation or has been disciplined for inappropriate prescribing of controlled substances.

**Patient Red Flags:**

- Individual insists on paying cash, or insists on paying cash for controlled substances even though insurance is on file.
- Evidence of “doctor shopping” exists.
- Evidence of “pharmacy shopping” exists.
- Individual resides outside of the trade area of your pharmacy.
- The individual’s statements and conduct or behavior suggest abuse of controlled substances.
- Individual asks for certain drugs prone to abuse by color, trade name or markings and/or uses “street names”.
- Individual routinely attempts to obtain an early refill on controlled substances.
- Individuals have suspicious relationships with each other. For example: multiple patients filling prescriptions from one address; prescriptions being presented by someone other than the patient; groups of patients arriving all with prescriptions for the same medication from the same doctor.
- The prescription is presented to the pharmacy by someone other than the ultimate user of the controlled substance or a member of his or her household.

**Prescription Red Flags:**

- Prescriptions presented represent a “cocktail” of commonly abused drugs or are presented in a combination that can cause medical complications. (i.e. an opioid, a benzodiazepine, and a muscle relaxant) This is often referred to as the “trinity” or “holy trinity.”
- Prescriptions for drugs with opposite effects. (e.g. stimulants and depressants)
- Prescriptions for drugs with similar effects. (e.g. multiple long acting or multiple short acting opioids)
- Prescription presented is for an unusually large quantity or high starting dose.
- Prescription appears to be altered or duplicated.
- Prescription has an electronically generated or rubber-stamped signature.  
**Please remember that a paper-based prescription for controlled substances must have a wet signature or it is not a valid**



## **POM 1311 Practice Compliance Corresponding Responsibility - Proper Prescriber Patient Relationship**

**prescription.**

### **Evaluating Red Flags**

When one or more red flags are present, further evaluation of the prescription is required. The pharmacist must use professional judgment to resolve all red flags prior to dispensing a controlled substance prescription. Document the results of the red flag evaluation in the Rx Notes field of Connexus. Pharmacists must use professional judgment and available resources when evaluating and resolving the red flags. **If the pharmacist cannot resolve every red flag, then the pharmacist should refuse to fill the prescription and document the refusal using the process outlined in this POM.** Below are some of the resources that a pharmacist may use to evaluate red flags:

- Patient profile;
- Prescriber consultation;
- Patient consultation;
- Drug Reference;
- State PMP/PDMP website (POM 1316: Prescription Monitoring Programs);
- POM 1703: Forged or Altered Prescriptions;
- POM 1317: Controlled Substance Prescriptions Written by Out-of-State Prescribers;
- POM 1318: Early Refill of Controlled Substance Prescriptions

Professional judgment may include knowledge or information from other pharmacists or prior experience with the prescriber or patient. It may also include knowledge that another pharmacy is refusing to fill a prescriber's prescriptions.

### **Verifying a Proper Prescriber-Patient Relationship**

In addition to evaluating all red flags, pharmacists must ensure there is a valid prescriber-patient relationship. If a pharmacist has a reasonable suspicion that a valid prescriber-patient relationship may not exist, the pharmacist must verify the relationship. The pharmacist should contact the prescriber by telephone to confirm the relationship exists.

In some states, telemedicine services are permissible. Refer to the Telemedicine guidance for state-specific guidelines which can be found [here](#). A prescription resulting from an internet-based questionnaire is invalid and may not be dispensed.

The following information may be relevant in evaluating the prescriber – patient relationship:



## POM 1311 Practice Compliance Corresponding Responsibility - Proper Prescriber Patient Relationship

- Confirmation of the patient's name and the name and quantity of the drug prescribed;
- Prescriber's diagnosis;
- Length of treatment;
- Date of the last physical examination.

Simply because the prescriber verifies that he or she has seen or treated the patient does not mean that an "appropriate" patient-prescriber relationship exists. If the pharmacist cannot reach the prescriber, he/she should exercise professional judgment to determine whether or not to fill the prescription. Additionally, even if the pharmacist is able to verify that an appropriate relationship exists, the pharmacist may still exercise his or her professional judgment and not fill the prescription

When the pharmacist takes steps to verify that a valid prescriber-patient relationship exists, and is able to resolve all other red flags, the pharmacist may dispense the prescription. In cases where the pharmacist takes steps to verify the prescriber-patient relationship, **the pharmacist must document the following in the Rx Notes field in Connexus:**

- (i) The pharmacist's initials;
- (ii) The name of the prescriber/prescriber's agent;
- (iii) The time of the conversation; and
- (iv) The notation "*proper relationship verified.*"

### Refusing to Fill the Prescription

Walmart supports pharmacists in their exercise of professional judgment to not fill a prescription. If a pharmacist determines that the controlled substance prescription should not be dispensed, **the pharmacist may not fill the prescription, and must** immediately complete the Refusal to Fill form.

Please refer to the detailed instructions on completing the Refusal to Fill form. Click here and select "Archer – Compliance."

This form provides important details about the prescription and prescriber that will allow Practice Compliance to evaluate and take appropriate follow-up action.

If possible, make a copy of the prescription to assist in completing the Refusal to Fill form. After completing the Refusal to Fill form, the pharmacist may shred the copy of the prescription. Failure to submit the Refusal to Fill form may result in disciplinary action, up to and including termination.



## POM 1311 Practice Compliance Corresponding Responsibility - Proper Prescriber Patient Relationship

The pharmacist should explain to the patient that he/she is unable to fill the prescription and return the original prescription to the patient, unless the pharmacist believes the prescription is forged or altered. Technicians or sales associates may not communicate the refusal to fill to a patient. This communication may be sensitive and should follow certain guidelines. Use the guidance to assist in communicating with the patient.

**Note** At all times the pharmacist must remain courteous and professional in communications with both prescribers and patients.

### Blanket Refusal to Fill

If, based on the pharmacist's professional judgment, a pharmacist identifies a pattern of red flags with a prescriber that are unresolvable, a pharmacist may refuse all controlled substance prescriptions from that prescriber ("Blanket Refusal") without evaluating every future controlled substance prescription presented from that prescriber. However, each controlled substance prescription from a blanket refused prescriber must be reviewed by the pharmacist so the refusal can be documented in Archer.

Each individual pharmacist must exercise independent professional judgment and make their own determination on a Blanket Refusal of a prescriber and **each pharmacist at a particular location must submit their own Blanket Refusal form for a prescriber**. If a pharmacist chooses to Blanket Refuse to fill controlled substance prescriptions from a prescriber, the pharmacist must follow these steps:

Step	Action Required
1	Pharmacist completes the Blanket Refusal <u>form</u> in Archer for the prescriber.
2	Pharmacist shares the decision to enter a Blanket Refusal with the Pharmacist in Charge (PIC) and all other pharmacists at the location. The PIC must ensure that all pharmacists at the location are aware of the circumstances surrounding the Blanket Refusal.
<div style="background-color: #cccccc; padding: 5px;"> <p><b>Note</b> This must occur through an oral communication. Do not post a list of refused prescribers, or other similar documentation, in the pharmacy.</p> </div>	
3	The pharmacist must document all subsequent controlled substance prescriptions from the prescriber using the (abbreviated) Refusal to Fill process in Archer (choose "Blanket Refusal" as "Reason").



**POM 1311**  
**Practice Compliance**  
**Corresponding Responsibility -**  
**Proper Prescriber Patient**  
**Relationship**

- 4** The pharmacist must communicate the decision with each patient when subsequent prescriptions from the same prescriber are presented, and communicate with the prescriber as necessary (e.g., e-prescriptions).

**Note** Technicians are prohibited from making a decision to Blanket Refuse a prescriber and must not communicate the Blanket Refusal to a patient. All communications related to refusals to fill must occur between the pharmacist and patient, or pharmacist and prescriber.

**Centrally Blocked Prescribers**

While pharmacists are in the best position to determine whether individual prescriptions are appropriate, additional information may be obtained that is not available to our pharmacists. Therefore, in certain situations, a prescriber may be identified whose prescribing practices raise concerns about prescribing controlled substances for legitimate medical purposes. After a thorough review, these additional insights may lead Walmart to place a block in Connexus on controlled substance prescriptions from these prescribers. This information will be communicated, as appropriate, to the prescriber and impacted pharmacies.

Controlled substance prescriptions for these prescribers will be blocked and will display the following message:

*CII-CV prescriptions for this prescriber have been centrally blocked from filling – see POM 1311 for details.*

If you receive the message above when attempting to fill a controlled substance prescription from one of these prescribers, the pharmacist must use these [guidelines](#) and [FAQs](#) for communicating this information to the patient. If you are contacted by the blocked prescriber, direct them to [RXCSComply@wal-mart.com](mailto:RXCSComply@wal-mart.com) or (479) 204-3461.

Based on your professional judgment, if you believe you should fill a controlled substance prescription for a prescriber who has been centrally blocked OR if you have any questions or concerns, please contact your Market Leader or Controlled Substances Compliance at [RXCSComply@wal-mart.com](mailto:RXCSComply@wal-mart.com).

Even in the absence of a Connexus blocked message, a pharmacist must not assume that controlled substance prescriptions from any prescriber meet the requirements for a legitimate prescription. Pharmacists must continue to evaluate every controlled substance prescription consistent with the exercise of the pharmacist's professional judgment and corresponding responsibility.



**POM 1311**  
**Practice Compliance**  
**Corresponding Responsibility -**  
**Proper Prescriber Patient**  
**Relationship**

Information gathered from the Refusals To Fill reported through Archer, among other data, is utilized to evaluate prescribers. Therefore, it is critical that pharmacists continue to follow the guidance in POM 1311/1703 and report all Refusals to Fill in Archer. This gives visibility to prescribers of concern and provides information needed to evaluate those prescribers.

**Conclusion**

Please do not hesitate to contact your Market Health and Wellness Director/Sam's Rx Market Manager or Practice Compliance if you have any questions regarding this information.

**Resources**

- Health & Wellness Market Leader
- Controlled Substance Compliance – [RXCSComply@wal-mart.com](mailto:RXCSComply@wal-mart.com)